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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,321	09/16/2005	Tatsuo Horizoe	0425-1214PUS1	8222

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	**PAPER NUMBER**
1649	

NOTIFICATION DATE	DELIVERY MODE
08/15/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/549,321	HORIZOE, TATSUO	
	Examiner	Art Unit	
	Stacey MacFarlane	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-23, drawn to an agent for treating an inflammatory bowel disease comprising of (a) at least one compound having an anti-inflammatory action and being selected from the group consisting of an aminosalicylic acid derivative, an anti-inflammatory glucocorticoid, a compound having an immunosuppressive action, an anti-TNFα antibody, a pituitary hormone and a compound having an anti-infective action as an active ingredient and (b) at least one compound having a PPARγ agonistic action as an active ingredient, wherein the agent is so configured that the compound (a) and the compound (b) are used simultaneously, separately or every scheduled time.

Group 2, claim(s) 24-26, drawn to use of the combination for producing an agent.

Group 3, claim(s) 27-29, drawn to a method for treating an inflammatory bowel disease comprising administering to a patient a pharmacologically effective amount of the combination of compound (a) and (b) of Group 1.

2. The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the single general inventive concept that permeates the groups is a combination of compound (a) and compound (b) of the claims. The expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of

the inventions makes over the prior art. Whether a particular feature makes a contribution over the prior art, is considered with respect to novelty and inventive step. In the instant application, the combination of compound (a) and compound (b) is taught by the prior art. The following reference teaches that 13 out of 15 patients received a concomitant therapy of a PPARγ agonist with corticosteroids and/or immunomodulator medications, such as azathioprine or 6-mercaptopurine (page 3323, paragraph 2 and Table 2). The prior art recites the common technical feature of Groups 1-3, thus, there is no special technical feature over the prior art and the application lacks Unity of Invention under PCT Rule 13.1.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(All Groups)

I. (Claim 1) Elect a single specific type of anti-inflammatory compound, or single specific combination thereof, from the list of Claim 1(a): an aminosalicylic acid derivative, an anti-inflammatory glucocorticoid, a compound having an immunosuppressive action, an anti-TNF-alpha antibody, a pituitary hormone, OR a compound having an anti-infective action as an active ingredient. And **further** electing a single specific species from the following:

(**A.**) For aminosalicylic acid derivative, elect one of the following: cyclosporin, azathioprine, 6-mercaptopurine, tacrolimus or methotrexate.

(**B.**) For anti-inflammatory glucocorticoid, elect one of the following: prednisolone, betamethasone, hydrocortisone, cortisone acetate, methylprednisolone, prednisone or budesonide.

(**C.**) For the anti-TNF-alpha antibody, elect one of the following: infliximab, etanercept, CDP-571, adalimumab, or CDP-870.

(**D.**) For the compound having an anti-infective action, elect one of the following: metronidazole, clarithromycin, tobramycin, ciprofloxacin hydrochloride, ampicillin, cefazolin, ofloxacine or levofloxacin.

II. (Claims 5-9) Elect a single PPARγ agonist from the species listed in Claim 5.

III. (Claims 19 and 20) Elect one of the following inflammatory bowel disease: ulcerative colitis or Crohn's disease.

IV. (Claim 1, 22, 23, 25 and 28) Elect one of the following modes of administration: simultaneous, separate or successive.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Currently there is no generic claim.

2. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent materially distinct combinations of compounds for the treatment of pathologically distinct diseases. Each product invention comprising a combination of compounds requires a separate search within the prior art, and each method for treating inflammatory bowel disease requires separate search and analysis of patentability depending upon the specific compound administered and specific disease treated.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, which also includes searching different electronic databases, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacey MacFarlane whose telephone number is (571)

270-3057. The examiner can normally be reached on Monday-Thursday 6:30AM-4:00 PM & ALT. Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

SNM

OLGA N. CHERNYSHEV, PH.D.
PRIMARY EXAMINER